

- 1 a. How large must a dosage form be to promote retention in the stomach in the  
2 fed state? Can an object be smaller than the pyloric diameter (in the fed state)  
3 and still promote retention? What evidence in the record supports the assertion  
4 that a dosage form of a particular size promotes retention?
- 5 b. At what time following immersion or ingestion is it critical that the drug form  
6 achieve a size sufficient to promote retention?
- 7 2. The phrase “about 15:85 to about 80:20” of claim 1 is directed to the ratio between the  
8 drug weight and the polymer weight, not solely to the polymer content. Given that the  
9 term “about” modifies a ratio, and not the absolute weight of the polymer content, the  
10 construction of that term should depend neither on a calculation solely factoring the  
11 polymer content, nor on a regulation directed to the tolerance for the polymer content  
12 in an approved product having a fixed, approved composition. How, then, would a  
13 person skilled in the art of drug dosage formulations understand the ratio to be  
14 modified by the term “about”?
- 15 3. Are artificial gastric fluids different from simulated gastric fluids? Describe the  
16 difference, if any, in a manner that can support a claim construction.
- 17 4. Does Depomed restrict the meaning of gastric fluid in claim 1 to only artificial or  
18 simulated gastric fluids and disclaim a meaning of fluid in the human stomach? And  
19 does this restricted meaning apply to claim 1 of both patents?

20 **IT IS SO ORDERED.**

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23 Dated: November 14, 2006



CHARLES R. BREYER  
UNITED STATES DISTRICT JUDGE